

Centers for Education & Research on Therapeutics™
a program of the Agency for Healthcare Research and Quality

BENEFIT THE PATIENT, MANAGE THE RISK

March 6, 2003
Marriott Crystal Gateway Hotel
Arlington, VA

■ CERTs RISK SERIES STRATEGIC SYMPOSIUM

	Participants
■	Government officials
■	Medical products industry executives
■	Consumers and patient advocates
■	Health care practitioners
■	Academics and researchers
■	Media
■	Representatives from the CERTs national program
	Objectives
■	To launch the research and education agenda from the five Risk Series Think Tanks
■	To refine the research agenda and expand commitments to adopt specific research areas
■	To discuss the Risk Series research agenda, establish priorities, and delineate next steps
■	To share and receive information with agencies and organizations on their programs affecting the management of therapeutic risk



CERTs Risk Series Strategic Symposium

No medical product can be 100% safe or effective. Everyone involved with the administration of healthcare must continually seek a balance between the risks and benefits of therapies as they are developed and used—a concept called "risk management." Over the past two years, experts from the government, medical products industry, media, consumer groups, and researchers convened a series of CERTs Think Tanks to review how risk is assessed, communicated, and managed. The result: The first national-scale research and education agenda from a public-private partnership.

Now, these ambitious plans will be unveiled to policymakers, elected officials, association groups, and others. Come help shape how our national healthcare system can move toward more effective management of therapeutic risk. Take part in discussions about positive ways to . . .

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Manage the Risk.

	Risk Series Think Tanks
■	Improving Communication of Drug Risk Information to Prevent Injury: *April 29 – May 1, 2001*
■	Postmarketing Assessments of Pharmaceutical Risk: *May 29 – 31, 2002*
■	Overcoming Difficult Issues in Characterizing Therapeutic Benefit: *September 17 – 19, 2002*
■	The Importance of the Media in Pharmaceutical Risk Communications: *January 7 – 8, 2003*
■	Managing the Risks of Therapeutic Products: *January 12 – 14, 2003*
	Focus Areas of the Risk Series Think Tanks
■	**Communication:** How are the risks of a therapy best communicated? How do the communication needs of the patient differ from those of the physician or the media?
■	**Assessment:** What are the information gaps in the current system for quantifying a therapy's risk? How can various sectors such as government, academia, and business work together more seamlessly?
■	**Management:** Once risk is identified, how do we minimize patient exposure to it? How do we tip the balance towards benefit? How do we maximize the likelihood that risks are prevented?
■	**Overall Prevention:** How can the concerns about risk communication and assessment be harnessed to prevent risk and its consequences?

Hosted by the Agency for Healthcare Research and Quality (AHRQ), the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA), Centers for Education and Research on Therapeutics (CERTs), and the Pharmaceutical Research and Manufacturers of America (PhRMA).

3rd Annual PATHs Meeting:

March 6, 2003, Marriott Crystal Gateway Hotel, Arlington, VA

	ACTIVITY	PRESENTERS
9:00 AM	Welcome & Orientation to the Program	Hugh H. Tilson, MD, DrPH Chair, CERTs Steering Committee Robert M. Califf, MD Principal Investigator, CERTs Coordinating Center Carolyn M. Clancy, MD Director, Agency for Healthcare Research and Quality (AHRQ)
9:10 AM	Highlights of the Risk Series Think Tanks	**Panelists:** Lynn A. Bosco, MD, MPH Director, Pharmaceutical Studies Center for Outcomes and Effectiveness Research, AHRQ William H. Campbell, PhD Principal Investigator, University of North Carolina CERTs Brian L. Strom, MD, MPH Principal Investigator, University of Pennsylvania CERTs Robert M. Califf, MD Principal Investigator, CERTs Coordinating Center Judith M. Kramer, MD, MS Principal Investigator, Duke University CERTs Paul J. Seligman, MD, MPH Director, Office of Pharmacoepidemiology and Statistical Science Center for Drug Evaluation and Research, US Food and Drug Administration Alan Goldhammer, PhD Associate Vice President, Science and Regulatory Affairs Pharmaceutical Research and Manufacturers of America
9:45 AM	Patient's Perspective on Research Agenda	Linda Golodner Executive Director, National Consumers League
9:55 AM	Clinician's Perspective on Research Agenda	Yank D. Coble, Jr., MD President, American Medical Association
10:05 AM	Public Health Perspective on Research Agenda	Georges Benjamin, MD, FACP Executive Director, American Public Health Association

3rd Annual PATHs Meeting: (CONTINUED)

March 6, 2003, Marriott Crystal Gateway Hotel, Arlington, VA

	ACTIVITY	PRESENTERS
10:15 AM	Managed Care Perspective on Research Agenda	Charles Cutler, MD, MS Chief Medical Officer, American Association of Health Plans
10:25 AM	Break	
10:40 AM	Roundtable Discussion	**Moderators:** Robert M. Califf, MD Principal Investigator, CERTs Coordinating Center Carolyn M. Clancy, MD Director, Agency for Healthcare Research and Quality (AHRQ)
11:40 AM	Closing Remarks	Hugh H. Tilson, MD, DrPH Chair, CERTs Steering Committee
11:45 AM	Adjournment	

3rd Annual Meeting of Partnerships to Advance THerapeutics (PATHs)

Benefit the Patient, Manage the Risk: CERTs Risk Series Strategic Symposium
Thursday, March 6, 2003
9:00 a.m. - 11:45 a.m.
Marriott Crystal Gateway Hotel, Arlington, VA

The Third Annual meeting of PATHs will be held on Thursday, March 6, 2003 from 9:00 a.m. to 11:45 a.m. at the Marriott Crystal Gateway Hotel, Arlington, VA.

The CERTs Risk Series Strategic Symposium is the unveiling of the research and education agenda culminating from the five nationally-recognized workshops conducted over the past two years addressing the management of therapeutic risk. These workshops on risk communication, risk assessment, benefit assessment, risk communication and media, and risk management were designed to examine and reshape how the nation assesses and manages the benefits and risks of therapeutics, and to stimulate more appropriate use of drugs and other therapeutics while improving therapeutic information to consumers and healthcare professionals.

At this meeting, we will discuss the research agenda, expand commitments to specific research areas, and delineate the next steps in furthering the management of therapeutic risk. Your expertise will add significantly to the range of perspectives represented, and help shape the discussion of this ambitious program to improve our national health care.

Please complete the information requested below and return the form to Julie Horiuchi, 3708 Mayfair Street, Suite 301, Durham, NC 27715, or fax: 919-489-7429 before February 7, 2003. If you have any questions or concerns, please do not hesitate to contact Julie at horiu002@mc.duke.edu.

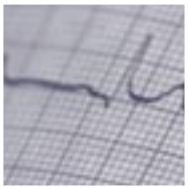
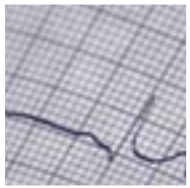
Please Check One:

☐ Yes, I will be able to attend ☐ No, I will not be able to attend

☐ Dr. ☐ Mr. ☐ Ms. ☐ Other_____

Name			Degree(s)	
Title(s)				
Department				
Organization				
Address	City	State	Zip	Country
Phone	Fax		Email	
Assistant Name	Assistant Phone		Assistant Email	

Return this form to Julie Horiuchi (Fax: 919-489-7429) by Friday, February 7, 2003.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